

## PREFILLED HYPODERMIC SYRINGE

### SPECIFICATION

#### FIELD OF THE INVENTION

The present invention relates to a hypodermic syringe.  
5 More particularly this invention concerns such a syringe that is prefilled.

#### BACKGROUND OF THE INVENTION

A standard hypodermic syringe comprises a hollow body holding a liquid medicament and a piston. An open end of the  
10 body carries an inner cap in which is seated a needle so that, when the piston is advanced, the liquid is expressed through the needle.

In order to maintain sterility before use, especially when the syringe is supplied prefilled to the user, it is  
15 standard to provide a protector cap over the needle. This cap is removed before use.

The manufacture of such a syringe is fairly complex, in particular because the needle and outer end of the assembly must be maintained sterile. Thus during assembly it is necessary to  
20 provide several sterilizing steps as the various parts are fitted

together. This manufacture is even more complex when high-temperature sterilization is required.

#### OBJECTS OF THE INVENTION

It is therefore an object of the present invention to  
5 provide an improved hypodermic syringe and method manufacturing same.

Another object is the provision of such an improved  
hypodermic syringe and method manufacturing same which overcome  
the above-given disadvantages, that is which produce a perfectly  
10 sterile prefilled syringe in a few simple steps.

#### SUMMARY OF THE INVENTION

A hypodermic syringe has according to the invention a  
hollow body adapted to hold a liquid and having an axially  
outwardly open end, an inner cap fitted over the body end, an  
15 axially extending needle seated in the inner cap and having an  
outer point projecting axially outward from the inner cap and an  
inner point projecting axially inward from the inner cap toward  
the body, and a washer between the inner cap and the body end  
having a central hole into which the inner point of the needle  
20 engages and provided with a membrane closing the hole and spaced  
axially inward from the inner point. An outer cap fittable over  
the inner cap and needle is connected to a clamp ring engageable

around the inner cap by a frangible web. Interengaging  
formations on the ring and on the inner cap releasably retain the  
outer cap in an outer position spaced axially outward of the body  
and in which an interior of the outer cap is open to the exterior  
5 and an inner position spaced axially closely to the body and in  
which the interior of the outer is not open to the exterior.

According to the invention the glass body can be  
subjected to high-temperature processes, e.g. siliconizing,  
before it is filled. In addition the membrane keeps the needle  
10 dry and out of contact with liquid medicament, so any reaction  
between the medicament and the metallic needle prior to use is  
impossible. Furthermore, the membrane is automatically pierced  
when the piston of the body is first advanced, since it will  
deform axially outward against the inner point of the needle.

15 Thus according to the invention after cleaning and  
filling the body, the inner cap and washer are mounted in place.  
The outer cap is fitted by its clamp ring to the inner cap in the  
outer position and the assembly is sterilized by a gaseous agent,  
e.g. hot air. Then the outer cap is pushed down to lock it in  
20 the inner position, in which in fact the formations secure the  
clamp ring so solidly to the inner cap that the web will fracture  
before the ring releases from the inner cap. For use the outer  
cap is snapped off the inner cap, exposing the outer point of the  
needle. Pressurization of the contents of the syringe forces the  
25 membrane against the inner point of the needle and punctures this  
membrane so the liquid can flow out through the needle.

According to the invention a liner cup is provided inside the outer cap, receiving the outer point of the needle, and clamped in the inner position between the outer cap and the inner cup. This cup is of rubber or a good-sealing elastomer. The inner cap is formed with a central outwardly extending projection from which the needle extends axially outward and that fits snugly in the liner cup in the inner position.

The body is normally cleaned and siliconized before is filled. In addition the body is filled without bubbles or air inclusions.

#### BRIEF DESCRIPTION OF THE DRAWING

The above and other objects, features, and advantages will become more readily apparent from the following description, reference being made to the accompanying drawing in which:

FIG. 1 is an exploded sectional view of a syringe according to the invention;

FIGS. 2, 3, and 4 are sections like FIG. 1 of the syringe in succeeding stages of assembly; and

FIG. 5 is a section showing the syringe when ready for use.

## SPECIFIC DESCRIPTION

As seen in the drawing, a standard syringe has a glass  
carpule or body 1 intended to hold a liquid medicament 11 and  
having as is well known in the art with an unillustrated plunger  
and a neck 1a centered on an axis A of the body 1. An inner cap  
2 of a somewhat flexible plastic fits snugly over this neck 1a  
and has a central axially outwardly extending projection 13 in  
which is seated a standard double-pointed needle 3 having an  
inner end or point 6 projecting axially inward slightly past an  
inner face 2a of the inner cap 2 and an outer point 15. The ring  
9 is formed with radially inwardly projecting bumps 9a that can  
engage in an outwardly open groove 2c of the inner cap 2 or in  
another groove 2d at the inner edge of this cap 2d as will be  
described below. An elastomeric washer 4 fits between the inner  
face 2a and the neck 1a and has at its inner face an elastic  
membrane 5 that is spaced in the assembled condition from the  
point 6.

A protector 7 centered on the axis A comprises a hard-  
plastic outer cap 8, a clamp ring 9 that can be formed by a  
plurality of axially extending arms separated by axially  
downwardly open slots, and a frangible web or weakened region 10  
connecting the ring 9 to the outer cap 8. A soft rubber liner  
cup 12 fits inside the outer cap 12 and has a rim 12a that can  
sit sealingly on an annular outer face 2b of the inner cap 2 and  
around the projection 13.

As a first step, the body 1 is cleaned, siliconized, and filled without bubbles with the liquid medicament 11.

Then as shown in FIG. 2 the liner cup 12 is fitted in the outer cap 8, the washer 4 is fitted inside the inner cup 2, and the bumps 9a of the ring 9 are fitted to the outer formation constituted by the groove 2c. In this position the rim 12a of the cup 12 is spaced from the end face 2b of the inner cap 8 so that the interior of the protector 12 is open to the exterior and a hot sterilizing gas as indicated at 14 can flood it and reach all critical interior surfaces.

This subassembly of the protector 7, cup 12, inner cap 2, and washer 4 is then fitted as shown in FIG. 3 to the syringe, in which case the inner cap snaps snugly in place over the neck 1a of the filled syringe body 1. Sterilizing can continue or be repeated in this position, since so long as the protector 7 is in the upper position its interior surfaces can be reached by the hot sterilizing gas 14.

Finally as shown in FIG. 4 the assembly is completed by pushing the outer cap 8 down on the inner cap 2 so the bumps 9a of the ring 9 move from the outer groove 2c to the inner groove 2d. In this position the rim 12a of the liner cup 12 sits flatly on the outer face 2b of the cap 2 and snugly around the projection 13, thereby isolating the outer portion of the needle 3 in a sterilized closed space. Once in this position the assembly can be handled without contamination, as the critical surfaces are wholly contained.

For use as shown in FIG. 5 the outer cap 8 of the protector 7 is snapped off the ring 9 by twisting or tipping it so as to fracture the web 10. Axially forwardly advancing the unillustrated piston in the body 1 will pressurize the liquid 11 and thereby deform the membrane 5 so it moves outward and is punctured by the inner point 6 of the needle 3, allowing the liquid 11 to exit through the needle 3